

## **REMARKS / ARGUMENTS**

### **Election/Restrictions**

Claims 31 to 53 stand restricted by the Examiner under 35 U.S.C. § 121 and § 372. Applicant is required to elect one of the following inventions:

Group I: Claims 31 to 42, drawn to a process for preventing or treating neurointoxication.

Group II: Claims 43 to 49, drawn to a gaseous inhalable medicament for the prevention or treatment of addiction.

Group III: Claims 50 to 52, drawn to a process for preventing or treating addiction.

Group IV: Claim 53, drawn to a process for the manufacture of all or part of an inhalable medicament.

In response to the requirement for restriction, Applicants elect, with traverse, Group II (claims 43 to 49) in the present application. The MPEP provides that a restriction requirement is only proper if there is a serious burden on the Patent Office to examine all of the claims in one application. Applicants respectfully maintain that the examination of all of the claims of the present application at once does not place a serious burden on the Patent Office as the claims are all directed to the particular medicament and its use. However, in view of the restriction, the Group I (claims 31 to 42), Group III (claims 50 to 52) and Group IV (claim 53) claims are withdrawn. Applicants reserve the right to file one or more division applications at a later date to cover the Group I, Group III and Group IV claims.

### **Disposition of the Claims**

The present response is intended to be a full and complete response to the Final Office Action mailed December 10, 2008. Claims 31 to 53 are pending in the present application. However, as noted above, claims 31 to 42 and 50 to 53 are

withdrawn from examination as being directed to a non-elected invention. Accordingly, the Group II claims, claims 43 to 49, are addressed with regard to the present reply. Claims 54 to 56 have been added and fall within the elected group. Applicants respectfully request continued examination of the Group II claims and the newly added claims and allowance of these claims.

### **Amendments to the Claims**

Claim 43 has been amended to indicate that the type of addiction is drug addition. In addition, claim 43 has been amended to incorporate the content of claim 45 therein. Claim 47 has been amended to correct dependency. Claim 48 has been amended to indicate that the type of drug addiction being treated is addiction to amphetamines and derivative thereof, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. Claims 54 to 56 have been added. Applicants respectfully request entry of these amendments.

### **35 U.S.C. § 112, First Paragraph, Rejection**

The Examiner rejects claims 43 to 47 and 49 under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while being enabling for treating drug addition, does not reasonable provide enablement for prevention or treatment of any and all addictions. This rejection is respectfully traversed with regard to claims 43, 44, 46, 47 and 49, as amended.

Applicants note that claim 43 has been amended to indicate that the type of addition is drug addition. In view of this amendment, Applicants maintain that claims 43, 44, 46, 47 and 49 are enabled. Accordingly, Applicants respectfully request that the rejection of claims 43 to 47 and 49 under 35 U.S.C. § 112, first paragraph, be withdrawn.

### **First 35 U.S.C. § 102(a) Rejection**

The Examiner rejects claims 42, 43, 46, and 48 under 35 U.S.C. § 102(a) as being anticipated by Homi et al, Anesthesiology 2003, 99, 876-881, (hereinafter "Homi"). Applicants believe that there is a typographical error in the present rejection and that the Examiner intended the rejection of the claims to read "43, 44, 46 and 48." Accordingly, the present rejection is respectfully traversed with regard to claims 43, 44, 46 and 48, as amended and newly added claims 54 to 56.

First, Applicants maintain that claims 43, 44, 46 and 48, as amended, and newly added claims 54 to 56 are not anticipated by Homi. As noted by the Examiner, Homi discloses a mixture of 35% xenon + 35% N<sub>2</sub>O + 30% O<sub>2</sub>. Claim 43, from which claims 44, 46 and 48 depend, has been amended to include the content of claim 45, which was not rejected by the Examiner in the present 35 U.S.C. § 102(a) rejection. Therefore, claim 43, as amended, indicates that the gaseous inhalable medicament comprises from 20% to 32% by volume of xenon and from 20% to 40% by volume of nitrous oxide. Accordingly, in view of this amendment, Applicants maintain that claims 43, 44, 46 and 48, as amended, and newly added claims 54 and 56 are not anticipated by Homi.

Second, Applicants maintain that as noted by the Examiner in the present rejection, Homi does not teach that the composition can be used in the manner instantly claimed—preventing or treating addiction. Therefore, for this additional reason, Applicants maintain that the claims are not anticipated by Homi since Homi fails to disclose a gaseous inhalable medicament that comprises from 20% to 32% by volume of xenon and from 20% to 40% by volume of nitrous oxide that is used for treating drug addiction.

In view of the above, Applicants respectfully request that the rejection of claims 43, 44, 46 and 48, as amended, and newly added claims 54 and 56 under 35 U.S.C. § 102(a) as being anticipated by Homi be withdrawn.

### **Second 35 U.S.C. § 102(a) Rejection**

The Examiner rejects claims 43, 44 and 48 under 35 U.S.C. § 102(a) as being anticipated by Mondain-Monval, U.S. Patent No. 4,820,258, (hereinafter "Mondain-Monval"). This rejection is respectfully traversed with regard to claims 43, 44 and 48, as amended, as well as newly added claims 54 and 56.

Applicants maintain that claims 43, 44 and 48, as amended, and newly added claims 54 to 56 are not anticipated by Mondain-Monval. As noted by the Examiner, Mondain-Monval discloses 50% to 80% by volume nitrous oxide, at least about 20% by volume oxygen and an inert gas xenon. Claim 43, from which claims 44 and 48 depend, has been amended to include the content of claim 45, which was not rejected by the Examiner in the present 35 U.S.C. § 102(a) rejection. Therefore, claim 43, as amended, indicates that the gaseous inhalable medicament comprises from 20% to 32% by volume of xenon and from 20% to 40% by volume of nitrous oxide. Accordingly, in view of this amendment, Applicants maintain that claims 43, 44 and 48, as amended, and newly added claims 54 and 56 are not anticipated by Mondain-Monval.

Applicants therefore respectfully request that the rejection of claims 43, 44 and 48, as amended, and newly added claims 54 and 56 under 35 U.S.C. § 102(a) as being anticipated by Mondain-Monval be withdrawn.

### **35 U.S.C. § 103(a) Rejection**

The Examiner rejects claims 43 to 49 under 35 U.S.C. § 103(a) as being unpatentable over Lecourt et al., U.S. Patent Publication No. 2002/0033174 (hereinafter "Lecourt") in view of Petzelt et al., WO/00/53192 (hereinafter "Petzelt") and Jevtovic-Todorovic et al, Nature Medicine, Volume 4, Number 4, April 1998 (hereinafter "Jevtovic-Todorovic") and Brooks, U.S. Patent No. 5,846,556 (hereinafter

"Brooks"). This rejection is respectfully traversed with regard to claims 43 to 44 and 46 to 49, as amended and newly added claims 54 to 56. Applicants note that claim 45 has been cancelled.

In the rejection, the Examiner notes that Lecourt teaches an inhalable medicament intended for the treatment of pain with a therapeutically effective amount of a mixture of several gases chosen from helium, oxygen, nitrogen, xenon, hydrogen, carbon monoxide, carbon dioxide, argon, krypton, nitrogen monoxide, nitrous oxide, carbonated hydrocarbons and fluorocarbons. The Examiner further states that it is the Examiner's position that all possible proportions of gases that are therapeutically effective are embraced by Lecourt. The Examiner goes on to state that Petzelt teaches gaseous mixtures of xenon with 5 to 90% by volume xenon and further contains oxygen and/or nitrogen and/or air, that Petzelt suggests mixing xenon with other gases harmless to humans and the use of the gas mixture for treating apoplexy (stroke) and craniocerebral trama. The Examiner then states that Jevtovic-Todorovic teaches a study to test the ability of nitrous oxide to protect neurons against excitotoxic action of N-methyl-D-aspartate, the gas mixtures comprising nitrous oxide and oxygen ranging from 20%, 40%, 80%, 150% and 180% nitrous oxide. The use suggested was neuroprotection against cerebral ischemic events that sometimes accompany surgery. The Examiner then cites Brooks as teaching compositions having 0 to 30% nitrous oxide.

The Examiner goes on to state that Lecourt does not expressly teach the instantly claimed amounts of xenon and nitrous oxide in the composition but that this deficiency is overcome by the teachings of Petzelt, Brooks and Jevtovic-Todorovic. Applicants respectfully disagree.

Applicants respectfully disagree and maintain that the present invention is not obvious in view of the references cited by the Examiner since one of ordinary skill in

the art, considering the references cited by the Examiner, would not be led to the specific formulation claimed by Applicants for the prevention or treatment of drug addiction.

The present invention comprises a gaseous inhalable medicament for the prevention or treatment of drug addiction, wherein the medicament comprises from 20% to 32% by volume of xenon and from 20% to 40% by volume of nitrous oxide in one embodiment and from 10% to 20% by volume of xenon and from 45% to 50% of nitrous oxide in another embodiment. In the present invention, the medicament is the xenon and nitrous oxide. As noted, this medicament is for the prevention or treatment of drug addiction.

The primary reference cited by the Examiner, Lecourt, discloses an inhalable aerosol medicament for the treatment or prevention of pain. In this application, Lecourt uses at least one gas in combination with at least one active product. The active product is chosen from among paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralocorticoids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine and morphine mimetics. The "at least one gas" is selected from a laundry list of possible gases. Applicants maintain that the objective of the reference is the delivery of an active product aided by the use of one or more gases. As noted in paragraph [0021] of Lecourt, the solution to the prior art problems for administering the active product is through the use of inhalation to administer the active substances to the patient. Lecourt does not disclose that the active product is optional (that the medicament can comprise simply a combination of gases).

Furthermore, Lecourt teaches that the combinations suggested by Lecourt are for the treatment of pain—not the treatment of drug addiction.

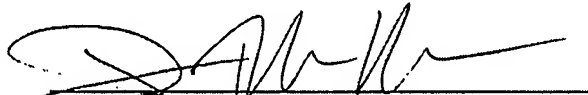
Finally, the Examiner states that the secondary references cited by the Examiner are sufficient to render the claims of the present application obvious. Applicants maintain that one skilled in the art, considering Lecourt in view of the secondary references would be led to believe that various combinations of nitrous oxide and xenon would be sufficient to be carrier gases for an active product such as those claimed in Lecourt for the treatment of pain. Applicants maintain that one skilled in the art, considering these references, would not be led to believe that a combination of nitrous oxide and xenon (without any active product such as those disclosed in Lecourt) could be used for the treatment of drug addiction.

In view of the above, Applicants maintain that claims 43 to 44 and 46 to 49, as amended, and newly added claims 54 to 56 are patentable over Lecourt in view of Petzelt, Jevtovic-Todorovic and Brooks. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 43 to 44 and 46 to 49, as amended, and newly added claims 54 to 56 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above, Applicants maintain that claims 43 to 44 and 46 to 49, as amended, and newly added claims 54 to 56 are now in condition for allowance. Early notice to this effect is earnestly solicited. Should the Examiner believe a telephone call would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney at the number listed below.

Respectfully submitted,



Donna Blalock Holguin  
Registration No. 38,082

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Air Liquide  
2700 Post Oak Blvd., Suite 1800  
Houston, Texas 77056  
Phone: (302) 286-5525  
Fax: (713) 624-8950